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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,823	08/22/2001	Corrado Fogher	B-4075PCT 618484-4	8610
36716	7590	12/22/2004	EXAMINER	
LADAS & PARRY 5670 WILSHIRE BOULEVARD, SUITE 2100 LOS ANGELES, CA 90036-5679			COLLINS, CYNTHIA E	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 12/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/743,823	FOGHER, CORRADO	
	<b>Examiner</b>	<b>Art Unit</b>	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 30 June 2004.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 59-90 is/are pending in the application.
- 4a) Of the above claim(s) 64-67,74-77 and 86-90 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 59-63,68-73 and 78-85 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 16 January 2001 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                                                |                                                                             |
|------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                                    | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)          |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                           | Paper No(s)/Mail Date. <u>0604</u> .                                        |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/01,4/02</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|                                                                                                                                                | 6) <input type="checkbox"/> Other: _____.                                   |

**DETAILED ACTION**

The amendment filed January 9, 2004 has been entered. In the amendment filed January 9, 2004, claims 1-28 were cancelled, claims 29-32, 35-36 and 38 were currently amended, and claims 59-90 were newly added.

The amendment filed March 1, 2004 has been entered. In the amendment filed March 1, 2004, claims 29-58 were cancelled. The Examiner acknowledges Applicant's request that the arguments submitted in the amendment be entered into the prosecution history. The arguments are not here addressed, however, because no art rejections were set forth in the restriction requirement mailed October 3, 2003. The references cited in the outstanding restriction requirement were not cited as art against the claimed invention. The references cited in the outstanding restriction requirement were cited to establish that the technical features linking the different groups of inventions are not special technical features. Where a group of inventions is claimed in a single international application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. Special technical features are those technical features that define a contribution over the prior art. A technical feature that does not define a contribution over the prior art is not a special technical feature. See PCT Rule 13.2. see also MPEP 1850.

The amendment filed June 30, 2004 has been entered. In the amendment filed June 30, 2004, claims 75 is currently amended.

A summary of the interview conducted June 21, 2004 is attached.

Applicant's election with traverse of invention V (claims 29-34 and 41-49, drawn to a plant expression cassette, including the 7s basic globulin promoter) in the reply filed on January 9, 2004 is acknowledged.

The traversal is on the ground(s) that under 35 U.S.C. § 121, the United States Patent and Trademark Office is authorized but not required to restrict an application to one invention if two or more independent and distinct inventions are claimed in one application, and that it is believed that restriction requirements should be issued only when absolutely necessary. Applicant respectfully requests withdrawal of the outstanding restriction requirement in view of the expenses that would be imposed upon the Applicant by multiple patent applications and multiple patents. (page 13 of the reply filed January 9, 2004)

This is not found persuasive because a search and examination of the multiple inventions claimed in the instant application would place an undue burden on the Office.

Claims 64-67, 74-77 and 86-90 are withdrawn from consideration as being directed to nonelected inventions.

The requirement is still deemed proper and is therefore made FINAL.

***Information Disclosure Statement***

Initialed and dated copies of Applicant's IDS forms 1449, filed January 16, 2001 and April 12, 2002 are attached to the instant Office action.

***Claim Objections***

Claims 59 is objected to because of the following informalities: claim 59 is directed in part to a nonelected invention (a regulation element of protein  $\beta$ -conglycine). Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 59-63, 68-73 and 78-85 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a plant expression cassette of allowing in-seed tissue specific expression of non-degraded human lactoferrin wherein a gene encoding the human lactoferrin is operatively linked to a regulation element of protein basic globulin 7S, including a plant expression cassette that includes the promoter of the gene coding for the protein basic globulin 7S, including a promoter having the sequence of SEQ. ID NO. 21. The claims are also drawn to said plant expression cassette wherein said cassette includes a leader sequence of the gene coding for the protein basic globulin 7S, including a leader sequence of SEQ. ID NO. 13. The claims are additionally drawn to said plant expression cassette wherein said gene encoding the human

lactoferrin has the sequence of SEQ ID NO. 1. The claims are further drawn to a recombinant DNA vector comprising said plant expression cassette.

The specification describes a plant expression cassette and recombinant DNA vector comprising a soybean protein basic globulin 7S promoter having the sequence of SEQ. ID NO. 21 operatively linked to a soybean protein basic globulin 7S leader coding sequence having the sequence of SEQ. ID NO. 13 operatively linked to operatively linked to a plant codon-optimized human lactoferrin coding sequence having the sequence of SEQ ID NO. 1, wherein said vector and cassette express non-degraded human lactoferrin in plant cells transformed therewith (pages 29-39; Figures 8 and 9).

The specification does not describe other regulation elements of the protein basic globulin 7S that can be used for in-seed tissue specific expression of non-degraded human lactoferrin, or other protein basic globulin 7S promoters obtained from soybean or from other plant species, or other protein basic globulin 7S leader sequences obtained from soybean or from other plant species, or other sequences encoding human lactoferrin designated as non-degradable, or other combinations of protein basic globulin 7S regulation elements and human lactoferrin coding sequences that can be used for in-seed tissue specific expression of non-degraded human lactoferrin.

The Federal Circuit has recently clarified the application of the written description requirement to nucleic acids. The court stated that “A description of a genus of cDNAs may be achieved by means of recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus.” See

*University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1569; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

In the instant case Applicant has not described a representative number of species falling within the scope of the claimed genus which encompasses numerous undisclosed and uncharacterized plant expression cassettes and vectors of varying composition and arrangement that would allow in-seed tissue specific expression of any type of sequence encoding human lactoferrin designated as non-degradable wherein any gene encoding the human lactoferrin is operatively linked to any type of regulation element of protein basic globulin 7S obtained from any organismal source, including the promoter of any gene coding for protein basic globulin 7S obtained from any organismal source and including any leader sequence of any gene coding for protein basic globulin 7S obtained from any organismal source, nor the structural features unique to the genus.

Claims 59-63, 68-73 and 78-85 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a plant expression cassette and recombinant DNA vector comprising a soybean protein basic globulin 7S promoter having the sequence of SEQ. ID NO. 21 operatively linked to a soybean protein basic globulin 7S leader coding sequence having the sequence of SEQ. ID NO. 13 operatively linked to operatively linked to a plant codon-optimized human lactoferrin coding sequence having the sequence of SEQ ID NO. 1, does not reasonably provide enablement for other plant expression cassettes and recombinant DNA vectors. The specification does not enable any person skilled in the art to which it pertains, or

with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to a plant expression cassette allowing in-seed tissue specific expression of non-degraded human lactoferrin wherein any gene encoding human lactoferrin is operatively linked to any type of regulation element of any type of protein basic globulin 7S, including a plant expression cassette that includes the promoter of any gene coding for any protein basic globulin 7S, including a promoter having the sequence of SEQ. ID NO. 21. The claims are also drawn to said plant expression cassette wherein said cassette includes any leader sequence of any gene coding for any protein basic globulin 7S, including a leader sequence of SEQ. ID NO. 13. The claims are additionally drawn to said plant expression cassette wherein said gene encoding the human lactoferrin has the sequence of SEQ ID NO. 1. The claims are further drawn to a recombinant DNA vector comprising said plant expression cassette, a method for using said vector according to claim 69 to transform vegetal cells, a vegetal cell including said vector of claim, a cellular aggregation obtainable from said cells, including calluses capable of regenerating transgenic plants, and a transgenic plant comprising said expression cassette, said plant expressing in-seed the non-degraded protein human lactoferrin.

The specification discloses how to make a plant expression cassette and recombinant DNA vector comprising a soybean protein basic globulin 7S promoter having the sequence of SEQ. ID NO. 21 operatively linked to a soybean protein basic globulin 7S leader coding sequence having the sequence of SEQ. ID NO. 13 operatively linked to operatively linked to a plant codon-optimized human lactoferrin coding sequence having the sequence of SEQ ID NO.

1, and how to use said vector and cassette to express non-degraded human lactoferrin in plant cells transformed therewith (pages 29-46).

The specification does not disclose how to make and use plant expression cassettes and recombinant DNA vectors for in-seed tissue specific expression of non-degraded human lactoferrin that comprise other types of protein basic globulin 7S regulatory element sequences, or that comprise other protein basic globulin 7S promoter or leader sequences, or that comprise other sequences encoding non-degradable human lactoferrin, or that comprise other combinations or arrangements of sequences.

The full scope of the claimed invention is not enabled because the effect of combining different types of regulatory elements with a protein coding sequence in a plant expression cassette is unpredictable, since the functionality of both the coding sequence and the regulatory elements may be differentially affected by the type and arrangement of sequences that make up the cassette.

The functionality of a coding sequence such as human lactoferrin may be positively or negatively affected by the presence or absence of particular regulatory elements within an expression cassette. See, for example, Mitra A. et al. (Expression of a human lactoferrin cDNA in tobacco cells produces antibacterial protein(s). Plant Physiol. 1994 Nov;106(3):977-81, Applicant's IDS), who teach that a tobacco suspension cell line transformed with a recombinant DNA vector comprising a native human lactoferrin coding sequence operatively linked to a CaMV 35S promoter produced only a truncated protein that was significantly smaller than the encoded full-length lactoferrin protein (page 977 abstract; page 979 paragraph spanning columns 1 and 2, Figure 2). Compare to Salmon V. et al. (Production of Human Lactoferrin in Transgenic

Tobacco Plants, Protein Expression and Purification, Volume 13, Issue 1, Pages 127-135, June 1998, Applicant's IDS), who teach that tobacco plants transformed with a recombinant DNA vector comprising a native human lactoferrin coding sequence operatively linked to an enhanced 35S CaMV promoter and either a polynucleotide encoding a signal peptide of human lactoferrin or a polynucleotide encoding a signal peptide of sporamin produced the encoded full-length lactoferrin protein (page 127 abstract; page 131 Figure 2).

Similarly, the functionality of a regulatory sequence such as a promoter located within an expression cassette may be quantitatively or qualitatively affected by the presence or absence of particular cis-acting nucleotide motifs within or near the promoter. See, for example, Shen Q. et al. (Modular nature of abscisic acid (ABA) response complexes: composite promoter units that are necessary and sufficient for ABA induction of gene expression in barley. Plant Cell. 1996 Jul;8(7):1107-19), who teach that while the coupling element CE3, obtained from the barley HVA1 gene promoter abscisic acid response complex (ABRC), is functional when located either proximal or distal to the ACGT-box of an ABRC operatively linked to a minimal promoter, the coupling element CE1, obtained from the barley HVA22 gene promoter ABRC, is functional only when located distal to the ACGT-box (page 1107 abstract; page 1113 Figure 4). Shen et al. also teach that while ABA induction of an ABRC containing the proximal CE3 is enhanced in the presence of the transcription regulator Vviporous1, ABA induction of an ABRC containing the distal CE1 is not (page 1107 abstract; page 1115 Figure 7).

In the instant case Applicant has not provided sufficient guidance with respect to the which regulatory elements should be combined with which lactoferrin coding sequences, or with respect to how to arrange these regulatory elements and lactoferrin coding sequences, in order to

form a plant expression cassette that is useful for in-seed tissue specific expression of non-degraded human lactoferrin. Absent such guidance it would require undue experimentation for one skilled in the art to make and use the claimed plant expression cassette constructs, as one skilled in the art would have to isolate from undisclosed sources and/or synthesize other types of protein basic globulin 7S regulatory element sequences, other protein basic globulin 7S promoter and leader sequences, and/or other sequences encoding non-degradable human lactoferrin, and then test each sequence combination for in-seed tissue specific expression of non-degraded human lactoferrin, in order to discriminate between operative and nonoperative embodiments encompassed by the claims. Such a trial and error approach to practicing the claimed invention would constitute undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 59, and claims 60-73 and 78-82 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 59 is indefinite in the recitation of “allowing in-seed tissue specific expression of non-degraded human lactoferrin”. It is unclear whether the claim requires that the expression cassette actually have the property of in-seed tissue specific expression of non-degraded human lactoferrin, as any plant expression cassette could allow for this property if appropriately modified.

Claim 59, and claims 60-73 and 78-85 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and

distinctly claim the subject matter which applicant regards as the invention. Claim 59 is indefinite in the recitation of “a regulation element of protein basic globulin 7S”. It is unclear how a gene coding sequence (DNA) would be operatively linked to a protein in the context of a plant expression cassette, as expression cassettes are ordinarily understood to comprise only DNA. It is also unclear what the protein basic globulin 7S element regulates, different protein parts regulate different biochemical activities.

Claim 60, and claim 61 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 60 is indefinite in the recitation of “includes”. It is unclear whether the plant expression cassette “includes” extra components in addition to the promoter of the gene coding for the protein basic globulin 7S.

Claim 62, and claim 63 dependent thereon, is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 62 is indefinite in the recitation of “includes”. It is unclear whether the plant expression cassette “includes” extra components in addition to the leader sequence of the gene coding for the protein basic globulin 7S.

Claim 70, and claim 71 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 70 is indefinite in the recitation of “includes”. It is unclear whether the plant expression cassette “includes” extra components in addition to the promoter of the gene coding for the protein basic globulin 7S.

Claim 72, and claim 73 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 72 is indefinite in the recitation of “includes”. It is unclear whether the plant expression cassette “includes” extra components in addition to the leader sequence of the gene coding for the protein basic globulin 7S.

Claim 78 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 78 is indefinite in the recitation of “includes”. It is unclear whether the plant expression cassette “includes” extra components in addition to the gene coding for human lactoferrin having SEQ ID NO:1.

Claim 79 provides for the use of the vector according to claim 69, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 80, and claims 81-82 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 80 is indefinite in the recitation of “includes”. It is unclear whether the vegetal cell “includes” extra components in addition to the vector of claim 69.

Claim 81, and claim 82 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 81 is indefinite in the recitation of

“obtainable from”. It is unclear whether the claim requires that the cellular aggregation be obtained from cells according to claim 80, or whether the claimed cellular aggregation may be obtained from additional cellular sources.

Claim 82 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 82 is indefinite in the recitation of “said aggregations”. There is insufficient antecedent basis for the limitation “said aggregations” in claims 81 and 82, as claims 81 and 82 are drawn to a singular cellular aggregation.

Claim 82 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 82 is indefinite in the recitation of “capable of regenerating transgenic plants”. It is unclear whether regenerating transgenic plants is required by the claim.

Claim 84 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 84 is indefinite in the recitation of “fruit bearing plants” and “horticultural plants”. It is unclear what type of plants are encompassed by the claims, as all angiosperms bear fruit, and any member of the plant kingdom may be used horticulturally.

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 79 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 59-60, 62, 68 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Watanabe Y. et al. (Nucleotide sequence of the basic 7S globulin gene from soybean. Plant Physiol. 1994 Jul;105(3):1019-20, Applicant's IDS).

The claims are drawn to a plant expression cassette allowing in-seed tissue specific expression of non-degraded human lactoferrin wherein a gene encoding the human lactoferrin is operatively linked to a regulation element of protein basic globulin 7, including a plant expression cassette that includes the promoter of the gene coding for the protein basic globulin 7S or that includes a leader sequence of the gene coding for the protein basic globulin 7S. The claims are also drawn to a recombinant DNA vector comprising said plant expression cassette.

Watanabe Y. et al. teach a plant expression cassette and recombinant DNA vector comprising a polynucleotide encoding protein basic globulin 7S operably linked to the promoter

of the gene coding for the protein basic globulin 7S and the leader sequence of the gene coding for the protein basic globulin 7S. While Watanabe Y. et al. et al. do not explicitly teach that their cassette would allow in-seed tissue specific expression of non-degraded human lactoferrin, Watanabe Y. et al. need not teach that their cassette has this property, since any plant expression cassette could allow for this property if appropriately modified. In this regard the Examiner notes that the rejected claims do not require in-seed tissue specific expression, or that the cassette comprise a gene encoding human lactoferrin, such that the rejected claims read on any plant expression cassette.

Claims 59, 68, 69 and 79-85 are rejected under 35 U.S.C. 102(b) as being anticipated by Salmon V. et al. (Production of Human Lactoferrin in Transgenic Tobacco Plants, Protein Expression and Purification, Volume 13, Issue 1, Pages 127-135, June 1998, Applicant's IDS).

The claims are drawn to a plant expression cassette allowing in-seed tissue specific expression of non-degraded human lactoferrin wherein a gene encoding the human lactoferrin is operatively linked to a regulation element of protein basic globulin 7S. The claims are also drawn to a recombinant DNA vector comprising said plant expression cassette, a method for using said vector according to claim 69 to transform vegetal cells, a vegetal cell including said vector of claim 69, a cellular aggregation obtainable from said cells including calluses capable of regenerating transgenic plants, and a transgenic plant comprising said expression cassette, said plant expressing in-seed the non-degraded protein human lactoferrin.

Salmon V. et al. teach plant expression cassettes and recombinant DNA vectors comprising a polynucleotide encoding human lactoferrin operably linked to an enhanced 35S

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promoter of CaMV and either a polynucleotide encoding a signal peptide of human lactoferrin, or a polynucleotide encoding a signal peptide of sporamin (page 130 Figure 1). Salmon V. et al. also teach the production of transgenic tobacco plants by transforming tobacco cells with said cassettes and vectors by Agrobacterium-mediated transformation of tobacco leaf discs, which process inherently involves cellular aggregations including calluses capable of regenerating transgenic plants (page 128 column 2 second full paragraph; page 130 column 1 *Generation of hLF-Expressing Transgenic Tobacco Plants*). The human lactoferrin expressed by the plants was non-degraded (page 132 paragraph spanning columns 1 and 2).

While Salmon V. et al. do not explicitly teach that their plants express the non-degraded protein human lactoferrin in-seed, their plants would necessarily express the non-degraded protein human lactoferrin in-seed, as the enhanced 35S promoter of CaMV is a constitutive promoter that drives expression of operatively linked sequences in all plant tissues. While Salmon V. et al. do not explicitly teach that their cassette would allow in-seed tissue specific expression of non-degraded human lactoferrin wherein a gene encoding the human lactoferrin is operatively linked to a regulation element of protein basic globulin 7S, Salmon V. et al. need not teach that their cassette has this property, since any plant expression cassette could allow for this property if appropriately modified. In this regard the Examiner notes that the rejected claims do not require in-seed tissue specific expression, or that the cassette comprise a gene encoding human lactoferrin operatively linked to a regulation element of protein basic globulin 7S, such that the rejected claims read on any plant expression cassette.

***Remarks***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins  
Examiner  
Art Unit 1638

CC

*Cynthia Collins 12/16/04*